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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,129	08/22/2003	Todd Bucciarelli	MBHB04-101-C	8860
<div>7590 08/17/2007 Dr. Kevin Noonan McDonnell Boehnen Hulbert & Berghoff 300 S. Wacker Dr. Chicago, IL 60606</div>			<div>EXAMINER BELYAVSKYI, MICHAEL A</div> <div>ART UNIT PAPER NUMBER 1644</div> <div>MAIL DATE DELIVERY MODE 08/17/2007 PAPER</div>	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/646,129

Applicant(s)

BUCCIARELLI ET AL.

Examiner

Michail A. Belyavskyi

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1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 and 63 is/are pending in the application.
- 4a) Of the above claim(s) 1-30 and 43-56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-42 and 57-60 and 63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendments filed on 06/25/07 is acknowledge.

Claims 1-60 and 63 are pending.

Claims 1-30 and 43-56 stand withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention.

Claims 31-42 and 57-60 and 63, drawn to an expression vector comprising a minimal promoter comprising TATA sequence and two phase tetracycline operators downstream from TATA sequence and two phased tetracycline operators downstream from TATA sequence are under consideration in the instant application.

In view of the amendment, filed 06/25/07 the following rejections remain:

3. The following is a quotation of the second paragraph of 35 U.S.C. 112.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 40-42 and 57, 58 and 60 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 40 is indefinite and ambiguous in the recitation of "wherein a gene encodes one or plurality of cyclin dependent kinase inhibitors". One skill in the art would know that one gene encode only one specific protein. It is unclear how one gene can encode plurality of cyclin dependent kinase inhibitors ?

6. Claims 57, 58 and 60 are indefinite and ambiguous in the recitation of "Cy motifs". The characteristics and metes and bounds of "Cy motifs" are unclear and indefinite, not defined by the claim and the specification does not provide a standard for ascertaining what Applicant means by "Cy motifs".

Given the absence of additional rebuttal to the outstanding rejections of record in applicant's amendment, filed 06/25/07 the rejections are maintained for the reasons of record.

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7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 57-60 and 63 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a New Matter rejection.**

“The expression vector of claim 31, wherein the expression vector encodes one or a multiplicity of Cy motifs under transcriptional control, claimed in claim 57; or wherein the multiplicity of Cy motifs are expressed as a peptide multimer thereof, recited in claim 58; or ; , wherein the Cy motifs encode a peptide having an amino acid sequence identified by SEQ ID

Nos:3,4,5,6,7,8,9,10,11,12,or 13 ” recited in claim 59; or wherein Cy motifs have the same or different amino acid sequence, claimed in claims 60 and 63 represent(s) a departure from the specification and the claims as originally filed. The specification and the claims as originally filed only support “The expression vector of claim 31, wherein the expression vector encodes cyclin-dependent kinase inhibitors selected from the group recited in claims 41 and 42.

Applicant's arguments, filed 06/25/07 have been fully considered, but have not been found convincing.

Applicant asserts that disclosure of the Specification on pages 19 –20 and in Table I fully supports claims 57-60 and 63.

Contrary to Applicants assertion, it is noted that specification on pages 19 and 20 only generally disclosed that peptides that may be used include Cy regions peptide. Moreover, page 19 of the Specification only provide a general disclosure that multimeric repeats of Cy motifs controlled by an inducible system are used to provide multiple Cy inhibitory species. Table I only disclosed several known peptides that have Cy motif in their sequences.

It is the Examiner position that the generic disclosure on page 19 and table I of the Specification does not support the specific recitation of “The expression vector of claim 31, wherein the expression vector encodes one or a multiplicity of Cy motifs under transcriptional control, claimed in claim 57; or wherein the multiplicity of Cy motifs are expressed as a peptide multimer thereof, recited in claim 58; or ; , wherein the Cy motifs encode a peptide having an amino acid sequence identified by SEQ ID Nos:3,4,5,6,7,8,9,10,11,12,or 13 ” recited in claim 59; or wherein Cy motifs have the same or different amino acid sequence, claimed in claims 60 and 63.

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The following new ground of rejection is necessitated by the amendment filed on 06/25/07

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 40-42 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a New Matter rejection.**

“wherein the gene encodes one or plurality of cyclin dependent kinase inhibitors” recited in claim 40 represent(s) a departure from the specification and the claims as originally filed. The passage pointed by applicant only disclosed that at certain embodiments CKI expression may be stimulated as the result of expression of heterologous copy of the CKI. More than one different heterologous CKI is introduced into the cell. It is the Examiner position that said passage does not support the claimed “**one gene encodes one or plurality of cyclin dependent kinase inhibitors**”.

10. No claim is allowed .

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskiy whose telephone number is 571/ 272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/ 272-0841.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MICHAIL BELYAVSKIY, PH.D.
PATENT EXAMINER

8/16/07